IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8442

Bartle, C.J. March 29, 2010

Nancy McDowell ("Ms. McDowell" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Doug Kondelik, Ms. McDowell's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert E. Fowles, M.D. Based on an echocardiogram dated March 22, 2002, Dr. Fowles attested in Part II of Ms. McDowell's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and a reduced ejection fraction in the range of

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(...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $549,753.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Alan A. Gabster, M.D., noted that Ms. McDowell had moderate mitral regurgitation with a ratio of 29%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. In addition, Dr. Gabster concluded that Ms. McDowell's pulmonary artery systolic pressure measured 46 mm Hg. Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic pulmonary artery pressure > 40 mm Hg measured by cardiac catheterization or > 45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id. § IV.B.2.C.(2)(b)I). Dr. Gabster also found that Ms. McDowell had an ejection fraction of 63%. An ejection fraction is

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4. Dr. Fowles also attested that Ms. McDowell suffered from New York Heart Association Functional Class IV symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Pulmonary hypertension secondary to moderate or greater mitral regurgitation and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim.

considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In January, 2004, the Trust forwarded the claim for review by Christopher M. Kramer, M.D., F.A.C.C., F.A.H.A., one of its auditing cardiologists. In audit, Dr. Kramer determined that there was a reasonable medical basis for the attesting physician's representation that claimant suffered from moderate mitral regurgitation and pulmonary hypertension secondary to moderate or greater mitral regurgitation. In addition, Dr. Kramer found that Ms. McDowell had an abnormal left atrial dimension, which is another one of the complicating factors needed to qualify for a Level II claim, but was not identified in claimant's Green Form. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view. See id. § IV.B.2.c.(2)(b)ii).[6] Based on the auditing cardiologist's findings, on March 11, 2004, the Trust issued a favorable post-audit determination with respect to Ms. McDowell's claim.

Following the Trust's issuance of its March 11, 2004 post-audit determination, but before it processed payment of

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6. Dr. Kramer, however, concluded that there was no reasonable medical basis for the opinion of Dr. Fowles that claimant had a reduced ejection fraction.

Ms. McDowell's claim, the Trust determined that certain claims that previously had been determined payable, including Ms. McDowell's claim, might be fraudulent. Class Counsel and Wyeth proposed a procedure to resolve these disputed claims. On November 22, 2006, we approved the procedure. See Pretrial Order ("PTO") No. 6707 (Nov. 22, 2006) ("Court Approved Procedure No. 13"). Claimant, however, elected not to participate in Court Approved Procedure No. 13. See Court Approved Procedure No. 13 ¶ 4.

Accordingly, the Trust forwarded the claim for review by Joseph A. Kisslo, M.D., whom the Trust engaged to review the integrity of echocardiogram system use during the performance of echocardiographic studies and the resulting interpretations submitted in support of certain claims. Dr. Kisslo detailed the findings of his review of Ms. McDowell's echocardiogram in a declaration dated February 8, 2007.[7] According to Dr. Kisslo, claimant's study exhibited "color pixel dominance, decreased Nyquist, overmeasurement of the [RJA], measurement of backflow and overmeasurement of the tricuspid regurgitant jet which served to exaggerate the apparent size and duration of Ms. McDowell's jet and the appearance of a complicating factor" as well as "persistence which also served to exaggerate the jet."

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7. Dr. Kisslo reviewed echocardiograms submitted in support of more than 600 claims. On November 9, 2004, Dr. Kisslo issued a report entitled Report of Joseph Kisslo, M.D. on the Integrity of Pre-Stay PADL Matrix Claims. He also issued individual reports relating to the claims he reviewed, including Ms. McDowell's claim.

Dr. Kisslo found that Echo Express, the mobile diagnostic services company that performed claimant's echocardiogram, routinely conducted echocardiograms that were "characterized by the use of excessive gain, apparent dominant color pixel allocation and the presence of color persistence, as well as marked errors in measurement of jets and structures ... [and] a concomitant use of decreased Nyquist settings."

Dr. Kisslo further concluded that claimant's true level of mitral regurgitation was mild, and that the attesting physician's finding of moderate mitral regurgitation was beyond the bounds of medical reason. Dr. Kisslo also concluded that Ms. McDowell's study created the appearance of pulmonary hypertension when none existed "by measuring beyond the envelope of [the] tricuspid regurgitant jet, thereby inflating the right ventricular systolic pressure ('RVSP')."

Based on Dr. Kisslo's findings, on February 9, 2007, the Trust issued a new post-audit determination rescinding its March 11, 2004 post-audit determination and denying Ms. McDowell's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Ms. McDowell contested this adverse determination.[8] In contest, claimant

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. McDowell's claim.

submitted an Expert Report from W. Marcus Brann, M.D. Dr. Brann dismissed Dr. Kisslo's Declaration as "a template in which he filled in names and a few numbers relevant to the study at hand ... [that] attempt[ed] to show ... that all of Echo Express's studies are suspect, regardless of the facts of the individual study." Dr. Brann noted that he reviewed "a number of studies performed by Echo Express," including some of the studies that Dr. Kisslo reviewed, and "came to similar conclusions that the regurgitant jets were not accurately measured." Nonetheless, Dr. Brann concluded that "Echo Express has performed studies that are technically adequate ...."

In addition, claimant asserted that the Trust's auditing cardiologist, Dr. Kramer, whom she described as the only "impartial unbiased" cardiologist to review the echocardiogram other than her own attesting physician, concluded that the representations on her Green Form were "medically reasonable." Ms. McDowell also contended that Dr. Kisslo's Declaration lacks specificity and contains "nothing more than unsubstantiated assertions." According to Ms. McDowell:

> Dr. Kisslo is critical of machine settings such as gain, Nyquist limit, color persistence and/or unreasonable tracings of the ratio between RJA and the LAA. However, none of the Kisslo Reports appear to specify what settings should have been used, either as a general matter or in light of the patient's body habitus or other clinical limitations associated with the study. Dr. Kisslo also fails to provide any statement of the "correct" RJA, LAA and resulting ratio that should have reasonably been reported.

Finally, Ms. McDowell argued that, to the extent her study contains inaccuracies, the Trust has failed to meet the legal requirements for intentional material misrepresentations. Specifically, Ms. McDowell stated that "[t]he Trust provides absolutely no evidence ... that the claimant herself has made any inaccurate statement at all, much less an intentional misrepresentation of material fact."

The Trust then issued a final post-audit determination, again denying Ms. McDowell's claim. In its letter, the Trust stated that the auditing cardiologist's inability to detect the alleged misrepresentations does not satisfy claimant's burden because the auditing cardiologist did not have "both specific knowledge of the echocardiogram machine employed by [Ms. McDowell's] provider, Echo Express, as well as experience with their history of manipulations and the manner in which they manifest themselves on the tape." The Trust also argued that Dr. Brann's report fails to provide a reasonable medical basis to support the claim because "[Dr. Brann] never addresses [Ms. McDowell's] particular claim nor disputes the specific findings made by Dr. Kisslo regarding [claimant's] echocardiogram and the mis-measurements and setting manipulations identified therein."[9] Moreover, the Trust noted that Dr. Brann concurred

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9. In support of this argument, the Trust asserted that the only study referenced in Dr. Brann's Report is one performed on a separate claimant and that Dr. Brann makes no mention of Ms. McDowell's study.

with Dr. Kisslo's conclusion that the regurgitant jets were measured inaccurately in a number of unidentified claims he reviewed.

Claimant disputed this final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. McDowell's claim should be paid. On July 26, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7332 (July 26, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C.,

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issues presented for resolution of this claim are whether claimant has met her burden in proving that: (1) there is a reasonable medical basis for the attesting physician's finding that she suffered from moderate mitral regurgitation and one of the complicating factors required under the Settlement Agreement; and (2) all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in the Green Form that are at issue and/or that the claimant intentionally misrepresented a material fact in connection with her claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers and that the claimant did not intentionally misrepresent a material fact in connection with her claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. McDowell relies solely on the arguments and evidence presented in contest. The Trust did not submit a reply to Ms. McDowell's response to the Trust's statement of the case.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that, although the study was not conducted in a manner consistent with medical standards, there was a reasonable medical basis for the attesting physician's Green Form representation that Ms. McDowell suffered from moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

> All of the usual echocardiographic views were obtained. However, the images were not conducted in a manner consistent with medical standards. There was excessive echo gain and excessive color gain causing color artifact even seen within the myocardial tissue. In addition, persistence with "stuttering" of cardiac images was noted with systolic color images seen during diastolic echo images.
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> I digitized the cardiac cycles in the apical two chamber and apical four chamber views. Visually, mild to moderate mitral regurgitation was noted in these views. In spite of excessive artifact and inappropriate demonstration of low velocity and non mitral regurgitant flow, I was able to accurately planimeter the RJA in the mid portion of systole. The largest RJA was noted to be in the apical two chamber view. This was planimetered at 5.7 cm2 in the mid portion of systole. This measurement was devoid of backflow. I was able to accurately determine the LAA on the study. The LAA in the apical two chamber view measured 28.5 cm2. Therefore, the largest RJA/LAA ratio was 20%.[11]
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11. Dr. Vigilante also found that "[t]he largest RJA in the apical four chamber view was 3.8 cm2. The left atrial area in the apical four chamber view measured 28.7 cm2. Therefore, the RJA/LAA ratio was 13% in the apical four chamber view."

> I was able to assess that there was a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, I was able to determine that the echocardiogram of March 22, 2002 demonstrated moderate mitral regurgitation with an RJA/LAA ratio of 20% in the apical two chamber view.

Dr. Vigilante also concluded that Ms. McDowell suffered from an abnormal left atrial dimension. In particular, Dr. Vigilante noted:

> Visually, the left atrium appeared enlarged. I digitized those cardiac cycles in the parasternal long axis and apical four chamber views in which the left atrium appeared the largest. I measured the left atrium by electronic calipers. I determined that the left atrial antero-posterior dimension was 4.5 cm. This measurement was taken between the posterior root of the aorta and posterior left atrial wall at the level of the aortic valve. This line was perpendicular to the supero-inferior axis of the left atrium. I determined that the left atrium measured 6.5 cm in the supero-inferior dimension. This measurement was taken from the mitral annulus to the posterior left atrial wall. This measurement was perpendicular to the mitral annulus. I excluded pulmonary vein structures in this measurement. The sonographer's left atrial measurement of 4.98 cm in the parasternal long axis view was inaccurate as this measurement occurred on a diagonal.[12]

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim, and that the representations of material fact in

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12. Dr. Vigilante also determined that there was no reasonable medical basis for the attesting physician's Green Form representations that claimant suffered from either pulmonary hypertension or a reduced ejection fraction.

connection with her claim are true. First, claimant's attesting physician reviewed her echocardiogram and found that she had moderate mitral regurgitation. Although the Trust challenged the conclusion of Dr. Fowles based on Dr. Kisslo's individual report, Dr. Vigilante confirmed the finding of moderate mitral regurgitation.[13] Specifically, Dr. Vigilante concluded that, "[i]n spite of excessive artifact and inappropriate demonstration of low velocity and non-mitral regurgitant flow, I was able to accurately planimeter the RJA in the mid portion of systole [and] accurately determine the LAA on the study," which "demonstrated moderate mitral regurgitation with an RJA/LAA ratio of 20% in the apical two chamber view." As noted above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for the attesting physician's Green Form representation that claimant suffered from moderate mitral regurgitation.

Second, we find that there is a reasonable medical basis for concluding that claimant suffers from an abnormal left atrial dimension, one of the complicating factors necessary for Level II benefits. See id. § IV.B.2.c.(2)(b)ii). Although the attesting physician did not indicate in Ms. McDowell's Green Form

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13. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

that she suffered from an abnormal left atrial dimension, both Dr. Kramer and Dr. Vigilante concluded that claimant has an abnormal left atrial dimension. Specifically, Dr. Vigilante found that claimant's "left atrial antero-posterior dimension was 4.5 cm" and her "left atrium measured 6.5 cm in the supero-inferior dimension." As stated above, the Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view. See id. Accordingly, we conclude that there is a reasonable medical basis for finding that claimant has an abnormal left atrial dimension.[14]

Finally, we find that claimant has satisfied her burden of proof with respect to the Trust's allegation that her claim is based on intentional misrepresentations of material fact. The Audit Rules define the burden of proof in show cause. See Audit Rule 24. Specifically, Audit Rule 24 provides, in relevant part, that:

> ... Where the Trust's Final Post-Audit Determination was based, in whole or in part, on the grounds that an intentional misrepresentation of a material fact was made in connection with the Claim, the Claimant

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14. In appropriate circumstances, such as those here where both the auditing cardiologist and a Technical Advisor have reviewed the key medical records submitted with a claim for Matrix Benefits, including the echocardiogram of attestation, a claimant may rely on the findings they have made in connection with their review to support a claim for Matrix Benefits.

> shall have the burden of proving that all representations of material fact in connection with the Claim are true.

In this instance, the representations of material fact in connection with Ms. McDowell's claim are true since we have found that there is a reasonable medical basis for the Green Form representation that claimant suffers from moderate mitral regurgitation and that claimant has an abnormal left atrial dimension. The presence of these two conditions qualify Ms. McDowell for Level II benefits.

Accordingly, Ms. McDowell is entitled to Matrix A-1, Level II benefits. We will reverse the Trust's denial of Ms. McDowell's claim for Matrix Benefits and the related derivative claim submitted by her spouse.